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# Lean Business Practice as Support to QMS Implementation in According to ISO 9001:2015

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**Abstract.** The contemporary market conditions impose increasingly strict requirements on organizations. Orientation towards product quality is one of the optimum strategies enabling survival and development in the ever more globalized market. The business practice required by ISO 9001 standard is often insufficient for an organization to survive in the market. Therefore many organizations, in addition to developing and implementing Quality Management System (QMS), optimize their operative processes by implementing the Lean tools. The paper provides a concept of interconnecting the ISO 9001:2015 standard requirements with the possible Lean tools deployment, which is to contribute to promoting effectiveness of the implemented QMS.

## 1. Introduction

The growth in productivity has nowadays brought about significant disproportion between the offer and demand of most industrial products. The manufacturing capacities installed are capable of producing much more products than the present day population needs. When this is joined with the achieved transport and communication systems improvements, we arrive to the basic reason for the developed world's decision to extend the free trade zone, which is named globalization today.

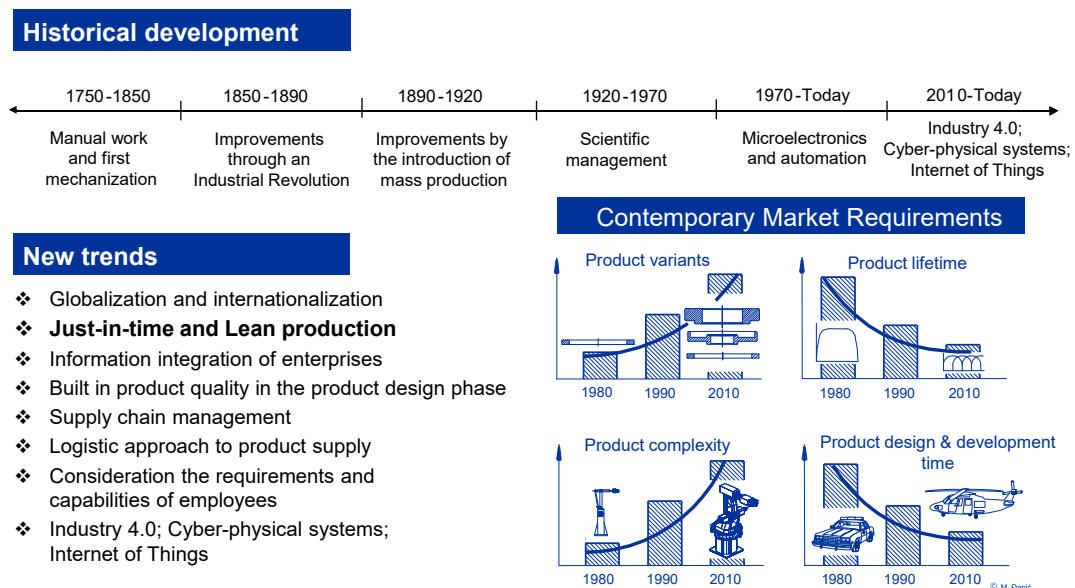
New and increasingly strict requirements have been imposed on manufacturing organizations (figure 1). On the one hand, these requirements are mirrored in more fierce competition, while on the other hand there have been continuous changes in customers' demands. For an organization to be competitive, it has to deliver products which fully meet customer's requirements, and it has to do this in the shortest time period and with the lowest costs related to the product's life. Survival of an organization is related to its capability to transform itself and fulfill these conditions. Those organizations which do not adapt to these changes and which do not find the way to satisfy customers do not have a chance to endure.

The decision to achieve satisfaction of customers through quality of products or services represents a major strategic change in many organizations. In that way, quality becomes the strategic tool by which competitive position is achieved, i.e. improving and maintaining quality becomes an important segment of the business strategy of any organization which wants to be the market leader.

Today, in product quality achievement, organizations typically rely on the international standards of the ISO 9000 series [1-3], i.e. on the requirements of the ISO 9001:2015 standard [1].

Is the business practice [4] imposed by the ISO 9000 series standards sufficient to respond to the contemporary market's requirements? It seems that it is not [5]. For that reason, many organizations striving to reach the best business practice, implement the Lean concept based on Toyota manufacturing system which has been developing since the beginning of the fifties of the last century until now [10-15].





**Figure 1. Manufacturing development trends**

This paper provides the concept of linking the Lean tools, ISO 9001:2015 standard requirements, PDCA planning cycles and levels, which certainly can contribute to improving the QMS implementation in organizations. With this aim in mind, first the answer is given to the question: What is the best business practice and how to define it? On the basis of that, a business practice is presented which is advocated by ISO 9001:2015 standard and by Lean concept. In the end, the concept (framework) is given on the basis of which integration is possible of Lean tools into the procedure of QMS implementation.

## 2. What is the best practice and how to define it?

The best practice is the concept we come across in everyday life and at work. The Internet search enables finding thousands of books, papers, studies, etc., which contain in their headlines, among other things, the words “best practice”. Few of these provide an explicit definition regarding what is understood by this concept. The reasons for this is probably that the authors believe it is the generally accepted concept understood by majority of people in the roughly the same way, so there is no need to define it specifically.

The similar situation is, for example, with the concept of “good engineering practice” appearing in the New Approach Directives within the EU technical legislation.

In order to reduce confusion and erroneous interpretations, it is necessary to have certain terms explicitly defined. As the confirmation of this, we shall use the Van Haren Publishing approach [4]. They have perceived that there is a great confusion in using the terms, and in understanding their meanings, such as in the case of “standard”, “best practice”, “body of knowledge”, “framework”, “guidance”, “method”, “model”, etc. With the aim of promoting and establishing consistent usage of these terms in their publications, they have defined meanings of the above terms, based on extensive analyses of the best practice and thanks to contributions of a wide group of stakeholders.

To achieve this, it is best to first define what the “practice” means. Thus, “practice” is defined as [4]: “the way in which professionals work within their profession, in order to carry out a specific task”. In that respect, “the best practice” can be defined as description of the best way of working based on the situation at hand”.

On the other hand, one of the world’s most renowned organizations in the field of quality, ASQ (American Society of Quality), defines “the best practice” [6] as: “A superior method or innovative practice that contributes to the improved performance of an organization, usually recognized as best by

other peer organizations“. Two things are important here. First, in order to consider a business practice as the best one, it has to enable significant improvement of the organization's performances. Second, such a practice has to be recognized by peer organizations as the best one.

The good practice is advocated, i.e. required, by the international ISO standards for management systems and is recognized by the widest grouping of stakeholders.

### 3. Best Business Practice and ISO 9001 Standard Requirements

The business management systems are established and implemented in order to enable:

- **good practice for conducting jobs and governing the organization at the management level** and to provide
- **consistent** (dependable, constant in the same manner, considered in the long run) **progress of activities**.

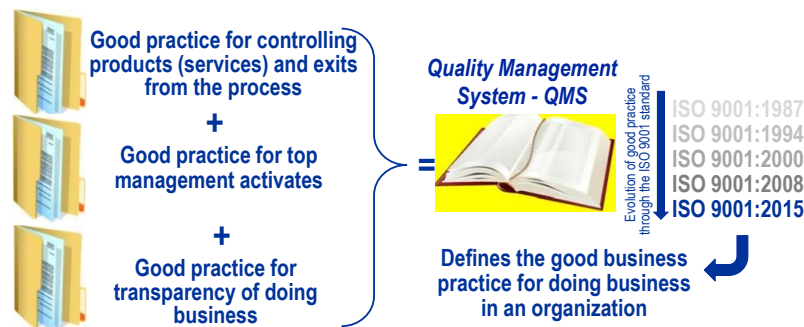
They contain multiple functions/disciplines. The implementation methods differ.

Thus, for example, Quality Management System (the management system for quality according to ISO 9001 standard requirements) – QMS, represents a part of an organization's management system which is oriented towards creating new and maintaining existing customers, through the processes: understanding customers' needs, planning, designing and delivering products and/or services which satisfy these needs.

As mentioned above, good practice is needed so that optimum output result can be provided, i.e. so that it has become the optimum method for ensuring these outputs. Good practice has in time been incorporated into the requirements of the standardized management systems.

According to [7], for instance, the good practice requirements have been incorporated into the ISO 9001 standard (figure 2), from the following three fields:

- Good practice for inspection of products/services and of processes outputs;
- Good practice for the top management activities aimed at supporting the good practice for inspection of products/services and process outputs.
- Good practice for transparency in tasks flow within organization



**Figure 2.** Good business practice incorporated into ISO 9001 standard (Adapted on the basis of [7])

Good practice is similar to a “movable target” as it changes and evolves continuously, which brings about a sort of management systems reviewing and improving every ten years or so. The management systems incorporate requirements for the good practice which was proven as valid in the previous period.

Consequently, if ISO 9001:2015 standard is observed and its changes with respect to the 2008 version, it can be stated that there are changes in the structure, terminology, requirements and in the elements that are more pronounced, but there are no changes in the purpose, objectives and scope of the standard implementation.

These changes in the requirements call for the organizations to implement about 18 % of new business practice requirements, to modify about 25% of the existing practices, to maintain the existing

practice in 50% and about 7% of requirements impose withdrawal of the previously implemented business practices according to the 2008 version requirements [8]. In taking into consideration the changes in the standards structure, as well as in term definitions, and the new and modified requirements, it can be stated that transition from the 2008 version to 2015 version represents the most voluminous modification (revision) of ISO 9001 standard so far [9].

Now it is expected from organizations to implement that practice through development, implementation and certification of their management systems by which they secure carrying out of business processes in a modern and transparent way.

#### **4. Lean Concept – As The Best Business Practice**

The Lean manufacturing concept has been developed by the Japanese automotive industry. The initiative has been led by Toyota through the development of the Toyota Production System (TPS), in striving after the WWII to renew the Japanese industry. The Lean concept was presented to the rest of the world by the book by Womack, Jones, and Roos “The Machine That Changed the World” in 1990 [11].

There is today an extensive literature that covers all the aspects of Lean, whether explaining what it is or explicating how to implement the concept in actual conditions. We are presenting the Lean concept in the way as it is given in references from [10] to [15].

Lean signifies a business philosophy which advocates elimination of unnecessary losses in all manufacturing activities which are connected with: workforce, suppliers, technologies, materials and inventory management.

Basically, Lean stands for a systematic approach to identifying and removing wastes through continual improvements of these ways, so that individual objects manufactured (parts, assemblies or products) are moved in the manufacturing pace determined (i.e. “pulled”) by customers’ requirements (external /internal), in the striving towards perfection, in the business sense of the word [10].

Lean production stands for everything that is opposite to mass production. The manufacturing process is to “flow” continually, so that: flow of materials is as linear as possible, without turbulences, unnecessary straying, holds and backward paths. Many companies today try to implement Lean manufacturing abandoning the mass production concept, with the goal of: (1) quality improvement, (2) eliminating manufacturing wastes, (3) reducing products delivery times and (4) decreasing overall costs. Lean production puts the accent on preventing possible wastes like those of additional: times, manpower or used materials which are paid by customers, but which do not contribute to increasing the product value. Manufacturing is focused on the requirements of actual buyers and not to requirements of imaginary possible buyers which the organization is yet to locate. Hence, nothing is manufactured for the stock.

And finally: *“Lean production uses only half of everything compared to the mass production. It only uses half of the human effort in the factory, half of the manufacturing space, half of the investment in tools and half of the engineering hours to develop a new product in half the time. It also requires keeping half less inventory, which all together results in a significant decrease of non-harmonized products, i.e. scrap”* [11].

In order for an organization to survive (achieve success) in the global market, it has to:

- Be oriented towards customers, their wishes, requirements and expectations – since today, there is much higher number of products than customers who are ready to buy these;
- To react quickly towards fulfilling customers’ requirements;
- To differ with regard to competition. Products of that organization have to be more innovative than those of competition and/or to differ regarding price, quality, etc.
- To continually improve its system.

All this can be achieved by fulfilling the Lean manufacturing goals, by application of Lean principles, i.e. by setting up and maintaining the Lean manufacturing systems. Now, having defined what is needed for an organization to be successful in contemporary conditions, let us see how Lean fits into these requirements.

The crucial idea behind Lean is to maximize the value for customer on the one hand and on the other hand to achieve this by minimizing wastes (holdbacks, scattering). In other words, the focus is on creating higher value for the customer by using: less resources, shorter time cycles, faster processing procedures and higher quality.

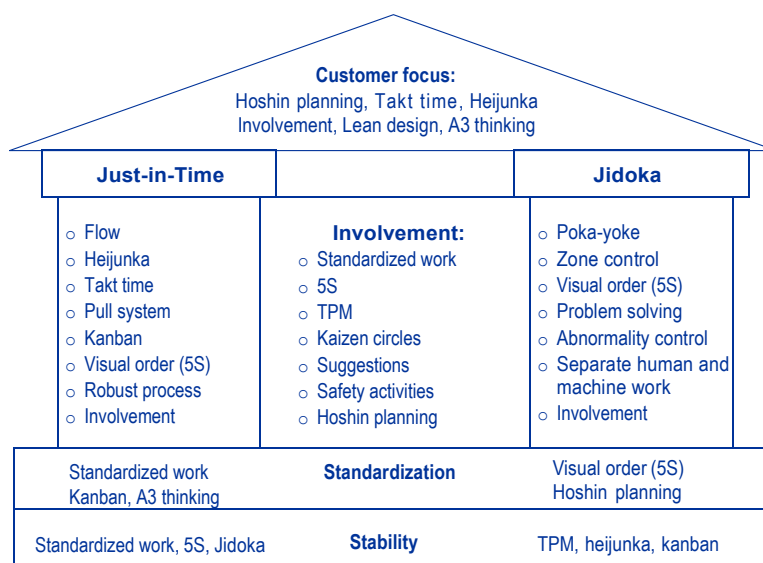
Lean initiative in any organization has four main goals:

1. Improvement of quality
2. Elimination of manufacturing wastes - scrap
3. Reducing the lead (main) manufacturing time
4. Reducing overall manufacturing costs.

If an organization is to reach the Lean goals, it has to implement into its business practice the set of Lean principles.

These principles are as follows:

- The Lean initiative begins so that the organization specifies values for its customers;
- Then it identifies the flow of values through the business-manufacturing processes which enable creating of value for the customer;
- Then, it has to ensure that the value creating activities flow continually;
- Manufacturing has to be “pulled” by the customer’s requirements, and
- All the previous steps have to be continuously upgraded until reaching perfection in the business sense of the word.



**Figure 3.** Toyota manufacturing system house (Adapted on the basis of [14])

Implementation of Lean tools and techniques (figure 3) on the operation level enables the company to satisfy their customers’ demands regarding quality of products or services, the time when products need to be delivered and the price at which this can be done. The Lean manufacturing tools create business and manufacturing processes that are agile and efficient. Lean business practice aids companies in managing their overall costs while shareholders receive return on their investments.

In the end, it should be said that these tools have not originated as the result of an “ad-hoc” innovative capabilities of engineers and other employees working in Toyota, but as systematic solutions which have lead to the fulfillment of the global goal set by Toyota at the beginning of the fifties of the previous century. Because, as Taiichi Ohno once said, “All we are doing (in Toyota) is looking at the time line, from the moment the customer gives us an order to the moment when we collect the cash. And we are

reducing the time line by reducing the non-value adding wastes. In order to reduce this time line, we had to eliminate all wastes, all scattering, i.e. all the activities which do not add value for the customer“. This was the global initiator and the objective which has brought about systematic development and implementation of all these tools.

### **5. Lean Business Practice as Support to QMS Implementation**

Lean business practice is nowadays considered the best business practice in the industry of individual material products, as covered by the term “manufacturing“.

On the other hand, if implemented in the right way, ISO 9001:2015 standard requirements will certainly upgrade the organization, i.e. they will bring about implementation of the good business practice. If, for instance, operative processes in product realization are observed, as covered by the requirements of the Clause 8, it can be asserted that these requirements are insufficient for operative processes to respond to the modern market requirements. This can be obvious if the two groups of requirements are compared. The first set of requirements relates to the requirements defined in ISO 9001 standards, while the second group relates to the requirements put forward by the market itself, relating to the conditions of survival in it (Figure 1). This deficiency was perceived by many, and one of the first ones was Juran in the 2000 version of the standard [5].

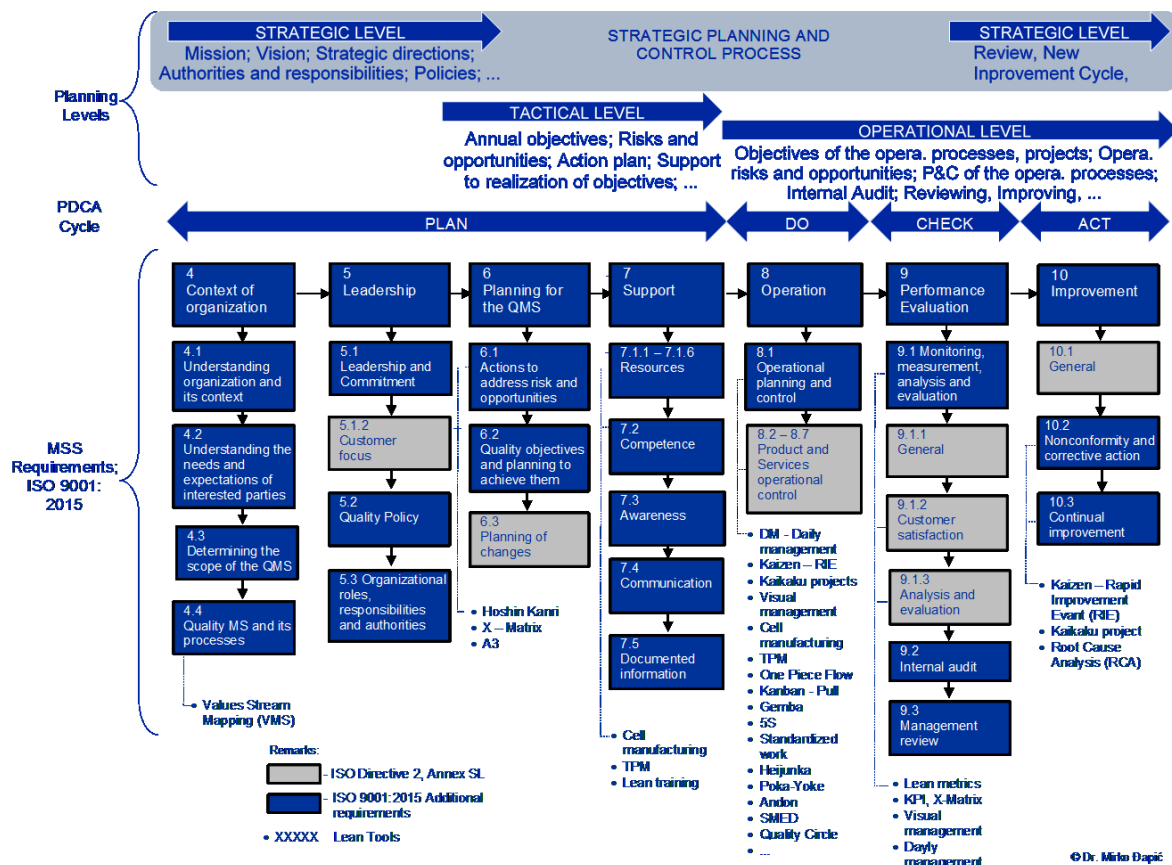
Therefore, for an organization to respond to the modern market requirements, its operative processes have to be meaningfully upgraded, i.e. the best business practice is to be implemented as offered by the Lean methods and tools (Figure 3), together with the Six Sigma concept implementation. Lean process provides for cleaning the processes of the observed shortcomings, i.e. losses and wasting, while Six Sigma provides for stabilization of these.

Lean tools implementation enables cleaning of the business processes errors, where manufacturing is focused only to what customers require, where inventories only consist of items necessary for that particular production, where manufacturing is “pulled” in the rhythm determined by customer’s requests, without bottlenecks or waiting. New “cellular” equipment arrangement is being introduced, with special attention directed to maintaining the equipment. The transition from one product series to the next has been optimized. Employees take meaningful participation in discovering and removing the observed errors. Implementation of Lean implies the process of continual improvements by organizing and implementing the “Rapid Improvement Event” – Kaizen) with participation of direct operators. On the other hand, as depicted in figure 4, QMS implementation according to ISO 9001:2015 requirements implies the deployment of PDCA cycles. It is therefore possible to identify clauses of the standard which are related to the segment “Plan” – Clauses 4, 5, 6 and 7, segment „Do“ - Clause 8, segment “Check“ - Clause 9 and segment “Act“ - Clause 10.

The development and implementation of QMS also tackles the organization’s activities in the strategic, tactical and operative levels.

In the strategic level, the organization’s business operation is defined through defining the mission, vision and strategic directions of the organization’s development in the period of three to five years. The business activities defined in this way are complemented by defining the authorizations and responsibilities, policies, principles and values that will be cherished by the organization’s members, i.e. these are to be adhered to in the process of reaching the strategic goals defined in the vision. All the above stated is contained in the strategic document named “The strategic plan for organizational improvement /development”. Related to the above stated, business processes are defined at the strategic level in the phase of QMS, together with their mutual connections in the procedure of delivering the products which have to satisfy customers and other interested organizations. In realizing these activities, it is very useful to apply the Lean VSM tool which relates to Value Stream Mapping.





**Figure 4.** Linkage of the organization planning level, PDCA cycles methodology, ISO 9001:2015 standard requirements and possible implementations of Lean tools

From the Lean tools point of view, it is possible, at the tactical level, to deploy several tools. Among the first, there is the Hoshin Kanri one which ensures deployment of quality goals and strategies from top towards lower organizational units, i.e. towards manufacturing processes. It is also useful, in the procedure of defining resources for action plan realization, to deploy the cellular manufacturing concept, i.e. to install connected cellular manufacturing systems which will be maintained in accordance with the Total Productive Maintenance, (TPM) concept. As regards upgrading of the employees' awareness, knowledge and capabilities, it is possible to apply the "Quality Circle" concept.

The operative level involves planning and management of business/manufacturing (operative) processes execution. The risks related to realizing these processes' goals are assessed, and possible opportunities are identified for their upgrading. Monitoring of their performances is done, as well as defining of possibilities for upgrading.

The major portion of the developed and implemented Lean tools is applied, especially in the automotive industry, at the operative level. Consequently, in implementing the Clause 8 of ISO 9001:2015 standard, an entire set of Lean tools can be used, as shown in figure 4. The analysis of these tools deployment possibilities goes beyond the aims and scope of this paper, since a detailed analysis of the Lean tool possible applications in satisfying the requirements of clauses 8, 9 and 10 requires much more space.

## 6. Conclusion

Contemporary market conditions have been posing new and ever more severe requirements to organizations. In the situation where there are much more products than customers ready to buy them,



many organizations discover an optimum strategy of survival and growth in their orientation towards product quality and also in the quality of the entire organization.

Today, the most widely spread approach to achieving product quality is through the process of developing and deploying the quality management system (QMS) according to the ISO 9001:2015 standard requirements. The business practice established in that way is insufficient for an organization to become a market leader. The orientation towards Lean & Six Sigma manufacturing philosophy is the very thing that has enabled many organizations to achieve that objective.

Following this trail, the paper analyses the business practice imposed by the new version of ISO 9001:2015 standard requirements and by the Lean manufacturing practice concept, i.e. analyses their compatibility. In realizing the operative processes, the implementation of ISO 9001:2015, analyses and improvements of these processes draw main benefits from implementing the Lean tools. For that reason, the operative level of Lean deployment is advocated, so that after cleaning the business-manufacturing processes from errors and after optimizing their performances, the obtained state is standardized and built in as the QMS constituent part. In that respect, many organizations, simultaneously with the QMS development and implementation, also optimize their operative business-manufacturing processes by deploying the Lean tools.

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